IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and all others similarly situated, JOSEPH MACKEN, and COMMISSIONER LINDA A. WATTERS	)	
Plaintiffs,	)	Civ. No. 05-075-SLR (Lead Case)
v.	)	
ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, LP,	)	
Defendants.	)	

DEFENDANTS' REPLY BRIEF
IN SUPPORT OF THEIR MOTION TO DISMISS

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Defendants AstraZeneca Pharmaceuticals LP and Zeneca Inc. (collectively "AstraZeneca") respectfully submit this Reply Brief in support of their Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint ("Complaint" or "Compl.").

I. PLAINTIFFS' OPPOSITION CONFIRMS THAT THEIR CLAIMS ARE PREEMPTED

Plaintiffs assert that this case is about "false statements and omissions of material fact." Plaintiffs' Opposition ("Opp.") at 2 (D.I. 43). Their Opposition confirms, however, that the omissions they seek to litigate are squarely preempted by federal law. It also confirms that Plaintiffs have not alleged any express false statements, and that the allegedly implicit messages they purport to find in AstraZeneca's ads are not actionable as a matter of law. Plaintiffs' Opposition thus confirms that their Complaint should be dismissed.

A. Plaintiffs Do Not Defend Their Omission Theory

Plaintiffs allege one core omission in their Complaint – the failure to disclose that "double the standard dose" of PRILOSEC® (omeprazole) is "equally as effective" as a 40 mg dose of NEXIUM® (esomeprazole magnesium) in healing erosive esophagitis. Compl. ¶¶ 77, 133. All of the alleged omissions are founded on this same core allegation.[1] Plaintiffs contend that AstraZeneca had to choose between making such a disclosure to avoid liability and not marketing its product at all. *E.g.*, Compl. ¶ 163. As AstraZeneca demonstrated in its Opening Brief ("Defs. Br.") (D.I. 33), however, because federal law bars AstraZeneca from making this very disclosure, Plaintiffs' claims are preempted, and attack conduct within the safe harbor of the

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[1] *See, e.g.*, Compl. ¶ 114 (alleging ads are "misleading by failing to mention that the exact same relief is 'possible'" with Prilosec); ¶ 129 (alleging ad "omits any reference to lack of clinical advantages of Nexium compared to Prilosec"); *accord id.* ¶¶ 121, 125, 127, 131, 133, 135, 137, 139, 141, 143, 145.

Delaware Consumer Fraud Act ("DCFA"). Defs. Br. at 18-22. In their Opposition, Plaintiffs do not seriously defend their claims of deceptive omissions.

As AstraZeneca previously showed, Plaintiffs do not and cannot dispute that the FDA has approved only a 20 mg daily dose of Prilosec for healing erosive esophagitis. *See* Prilosec Labeling at, 25 (Request for Judicial Notice ("RJN"), Ex. 2 (D.I. 34)); *see also id.* at 12-13. The FDA bars the "off-label" advertising of non-approved dosages, and Plaintiffs do not even suggest otherwise. *See* 21 C.F.R. § 202.1(e)(4)(i)(a); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998), *vacated in part on other grounds*, 202 F.3d 331 (D.C. Cir. 2000); *see also* 21 U.S.C. § 352(n); *cf. Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 942 (7th Cir. 2001). The FDA will not permit AstraZeneca to "recommend or suggest" in its advertising that doctors should prescribe or that patients should take more than 20 mg daily of Prilosec to heal erosive esophagitis, and thus bars AstraZeneca from making the allegedly omitted claims of equal efficacy. Yet this is precisely the information that Plaintiffs contend should have been included in every Nexium ad under state law. This is conflict preemption in its starkest form. Defs. Br. at 19-22; *see also Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000); *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 11 (Cal. 2004).

In response, Plaintiffs conspicuously do not dispute – and thus tacitly concede – that federal law preempts the allegedly necessary disclosures. Instead, they recharacterize their Complaint as raising "speculations about how [AstraZeneca] might respond to a damages award." Opp. at 19. This about-face does not help them. The only "omissions" alleged in the Complaint that could provide a basis for liability are those involving a double-dose of Prilosec, because only a double-dose of Prilosec is alleged to be equally as effective as Nexium at treating erosive esophagitis. *See* Compl. ¶¶ 50, 52, 54, 58, 77. Because the FDA bars manufacturers

from promotion that recommends or suggests an unapproved dose, this omission claim is preempted. Plaintiffs offer no responsive contrary argument.

Because this is a case of conflict preemption, Plaintiffs' reliance on cases rejecting "field" preemption and express preemption under the FDCA is misplaced. *See* Opp. at 20-23; *e.g., Consumer Justice Ctr. v. Olympian Labs, Inc.*, 121 Cal. Rptr. 2d 749 (Cal. Ct. App. 2002); *In re Paxil Litig.*, 2002 WL 31375497, at *1 (C.D. Cal. Oct. 18, 2002); *Zenith Labs., Inc. v. Abbott Labs.*, 1996 WL 33344963, at *4-5 (D.N.J. Aug. 7, 1996). Although Plaintiffs heavily rely on *Consumer Justice Center*, that case in particular illustrates why Plaintiffs' argument is untenable. The claims there involved over-the-counter dietary supplements, not prescription drugs. 121 Cal. Rptr. 2d at 751. The court concluded that field preemption did not apply, but did so because Congress had expressly exempted dietary supplements from the FDA pre-market approval process that applies to pharmaceutical products. *Id.* at 755-56. The court nonetheless went on to address conflict preemption in the context of a federal statute that applies to food, but not prescription drugs. *Id.* at 756-57. Nothing in *Consumer Justice* suggests that ordinary conflict preemption principles should be suspended when a plaintiff challenges the advertising of a prescription drug – and they are not. *See Dowhal*, 88 P.3d at 11.

Plaintiffs' citation to *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876 (E.D. Tex. 2005), is similarly unhelpful (*see* Opp. at 19), because the reasoning behind the finding of no preemption in that failure-to-warn case was that FDA regulations do not bar manufacturers from adding warnings to their labeling, and arguably even encourage such additions. *Id.* at 883-84. The FDA specifically prohibits AstraZeneca, however, from promoting the message at issue here – equality based on a non-approved dosing regimen of Prilosec. AstraZeneca thus has not asserted that the Food Drug and Cosmetic Act ("FDCA") preempts all state-law claims of false

advertising. *See* Defs. Br. at 25. AstraZeneca argues instead that Plaintiffs' claims conflict with and frustrate the purposes of the FDCA and of FDA regulations. Such conflict preemption arguments are valid. *See, e.g., Dowhal*, 88 P.3d at 11 (holding that state law is preempted where the disclosure plaintiff seeks conflicts with an FDA-approved disclosure); *see generally Geier*, 529 U.S. at 873; *Lawrence County v. Lead-Deadwood Sch. Dist. No. 40-1,* 469 U.S. 256, 260 (1985). Plaintiffs have offered no authority to the contrary. Accordingly, their claims are preempted.

Finally, Plaintiffs provide no meaningful answer to the holding in *Bober*, 246 F.3d at 941-42, that because federal law barred the disclosure about the effectiveness of a "double dose" of Zantac that the plaintiff contended should have been made, liability under state law for deceptive advertising was precluded. Their double-dose claims fail for the same reasons as those in *Bober*. Although the plaintiff in *Bober* did not attempt to attack the defendant's entire advertising campaign for its FDA-approved drugs, under the principles set forth in *Bober*, any such attempt would fail *a fortiori*. *Bober* makes clear that communications that are consistent with the FDA's labeling and regulations are not actionable under state law that permits conduct "specifically authorized" by federal law. *Bober*, 246 F.3d at 942; *see also* 6 *Del. C.* § 2513(b)(2); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 177 (N.J. Super. Ct. App. Div. 2003).

B. Plaintiffs Identify No Statements That Are Outside The Nexium Labeling

With Plaintiffs' omissions theory of liability squarely preempted, Plaintiffs are left to contend only that the ads contain false statements or implicit messages that are misleading on their own, apart from any non-disclosure. Their Opposition confirms that they have entirely failed to plead any actionable claim of this kind.

AstraZeneca has previously demonstrated that ads that are consistent with FDA-approved labeling are not actionable under state law, and that state-law claims that challenge such ads are preempted. *See* Defs. Br. at 16-18; *see also, e.g., Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (granting motion to dismiss to the extent that challenged statements "comport substantively," even if not "precisely," with the FDA-approved labeling). Plaintiffs apparently concede the correctness of this framework. *See* Opp. at 1-2, 25-26. They have identified no advertising statements that meet this standard.

1. Plaintiffs Have Not Identified Any Allegedly False Statements

As shown below, every one of the statements Plaintiffs challenge (*see* Opp. at 7-8) is true on its face as to Nexium, and Plaintiffs do not contend otherwise. Each statement is fully consistent with the FDA's approval of the "new drug application" for Nexium for the indications reflected on the FDA-approved labeling and therefore, as a matter of law, cannot be treated as false or misleading. Nexium is indisputably "purple" and "from the makers of Prilosec." *E.g.*, Compl. ¶¶ 6, 7. Plaintiffs also do not and cannot dispute that Nexium can "Relieve the heartburn" or that Nexium provides "healing" or can "Heal the damage" of erosive esophagitis. The statement that relief is "possible" with Nexium is a truthful and appropriately cautious statement, given that Nexium – while highly effective at healing and providing relief of symptoms – does not have a 100 percent rate of healing, as reflected in the results of clinical studies that appear on the Nexium labeling. *See* Nexium Labeling at 13-20 (RJN, Ex. 1). Plaintiffs concede that they "do not allege that Nexium was not as safe or effective as indicated in its labeling." Opp. at 13. In any case, the FDA-approved Nexium labeling reflects that Nexium has been approved as safe and effective for treatment of the symptoms of GERD and for

healing erosive esophagitis, so these statements are true as a matter of law. Nexium Labeling at 23 (RJN, Ex. 1).[2]

The statement that Nexium is "powerful" is fully consistent with the FDA's approval of Nexium as safe and effective and, in any event, is at most non-actionable puffery. *See Cytyc*, 12 F. Supp. 2d at 300-01 (holding that statements such as "the new 'Gold Standard'" and "presents cells with unprecedented clarity" were non-actionable puffery); *New Jersey Citizen Action*, 842 A.2d at 177 (holding that statements in direct-to-consumer advertising such as "you . . . can lead a normal nearly symptom-free life again" were "merely expressions in the nature of puffery and thus are not actionable").

The description of Nexium as "new" similarly was true and cannot support a false advertising claim: the FDA approved the "new drug application" for Nexium (Compl. ¶ 6; *see also* 21 U.S.C. § 355(b)), which affords the sponsor six months from the date of launching the product in which to advertise its product as "new." *See FDA Division of Drug Marketing, Advertising, and Communications Frequently Asked Questions*, available at http://www.fda.gov/cder/ddmac/FAQS.HTM#new (last visited August 24, 2005); 3 Trade Reg. Rep. (CCH) ¶ 7765 n.20 (citing Federal Trade Commission Advisory Opinion #120).

Plaintiffs also assert that AstraZeneca's ads "claim[ed that] Nexium was superior to Prilosec," *see, e.g.*, Compl. ¶ 90, but none of the ads quoted in or attached to Plaintiffs' Complaint contains any such express statement of superiority. Indeed, only two of the four television ads and six of the twelve print ads quoted in or attached to the Complaint even

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[2] Whether Plaintiffs think Nexium is not "very" effective at relieving symptoms (Compl. ¶ 137) is irrelevant, given that the FDA has approved Nexium as effective for treatment of symptomatic GERD, and Plaintiffs state that they do not challenge that decision. *See* Opp. at 13; Nexium Labeling at 23 (RJN, Ex. 1).

mention "Prilosec," let alone make a claim of superiority of Nexium over Prilosec. *See* Compl. ¶¶ 112-13, 123-24, 126, 128, 130, 134. Thus, Plaintiffs' unsupported assertion that the "overarching" theme of AstraZeneca's advertisements was that Nexium was superior to Prilosec (Opp. at 7), is contradicted by the actual advertisements attached to the Complaint. In such a situation, the attached documents control and the inconsistent allegations are disregarded. *See, e.g.*, *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994) ("Where there is a disparity between a written instrument annexed to a pleading and an allegation in the pleading based thereon, the written instrument will control.").

In sum, every statement in the challenged ads to which Plaintiffs point in their Opposition is true as a matter of law. Every statement is supported by and within the FDA-approved Nexium labeling. *See Cytyc*, 12 F. Supp. 2d at 301 (holding that statements that "comport substantively," even if not "precisely," with the FDA-approved labeling are neither false nor misleading as a matter of law); *accord SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 1996 WL 280810, at *13 (S.D.N.Y. 1996); *Kanter v. Warner-Lambert Co.*, 122 Cal. Rptr. 2d 72, 84-85 (Cal. Ct. App. 2002); *American Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987). Plaintiffs' attack on these statements thus is precluded under Delaware law and is preempted. *See* 6 *Del. C.* § 2513(b)(2); *Bober*, 246 F.3d at 941-42; *American Home Prods.*, 672 F. Supp. at 144. Accordingly, their claims should be dismissed.

2. Plaintiffs' Claims Of Implied Messages Are Not Actionable

Having failed to allege any overt false statements, Plaintiffs allege two ways in which AstraZeneca's ads contain an *implied* message that Plaintiffs contend is outside the Nexium labeling. First, Plaintiffs allege that the ads contain an implicit message of "superiority" to Prilosec. This is the theory asserted in their Complaint. *E.g.*, Compl. ¶ 7. As this is untenable,

their Opposition also presents a second and new allegation, that by saying healing and relief are "possible" with Nexium, AstraZeneca is falsely implying that healing and relief were not possible with Prilosec. Opp. at 7-8. Neither theory is actionable.

a. Plaintiffs' Claims Of An Implied Message Of "Superiority" Are Not Actionable

Plaintiffs' first theory of an implied message – that Nexium is better than Prilosec at healing or providing relief – is not actionable, because that same message is implicit within the FDA-approved Nexium labeling. *See* Defs. Br. at 14-15.

Plaintiffs concede that they are not challenging the effectiveness of Nexium as stated on the labeling. Opp. at 13. Plaintiffs have also conceded that in studies that are reflected on the Nexium labeling, Nexium 40 mg was shown "more effective" and to have "higher healing" rates than Prilosec 20 mg in healing erosive esophagitis. Compl. ¶¶ 50, 54, 58; Nexium Labeling at 13-14 (RJN, Ex. 1). These concessions are dispositive as they concede that the Nexium labeling contains the very same implicit message of "superiority" that Plaintiffs purport to find in AstraZeneca's ads – a drug that is "more effective" and has "higher healing" rates that the approved dosage of another drug.

A message consistent with FDA-approved labeling is not actionable as a false statement. *See*, *Cytyc Corp.*, 12 F. Supp. 2d at 301; *Bober*, 246 F.3d at 942. Plaintiffs do not dispute this principle of law. *See*, Opp. at 1-2, 25-26. They contend only that the label conveys no message of superiority because the FDA's approval of a 40 mg dose for healing erosive esophagitis was premised only on Nexium being superior to placebo. Opp. at 1, 5. This is false. It is belied by Plaintiffs' Complaint, ¶¶ 48-61, and by the labeling itself, which shows that it was clinical studies comparing Nexium 40 mg to Prilosec 20 mg in erosive esophagitis patients – not studies comparing Nexium to placebo – that provided the "substantial evidence" of safety and efficacy

that supported the FDA's approval of a 40 mg dose of Nexium for healing erosive esophagitis. *See* 21 C.F.R. § 314.125(b)(5); *see also* 21 U.S.C. § 355(b); 21 C.F.R. § 314.50(c)(2)(i); 314.105(c); 314.126. These are the only clinical studies reflected on the labeling for this indication.[3] Nexium Labeling at 13-14 (RJN, Ex. 1). It is also belied by the FDA's decision to reject the recommendation of the medical reviewer to approve only a 20 mg dose.

In *New Jersey Citizen Action*, 842 A.2d 174, for example, the plaintiffs challenged the advertising of Claritin products with DTC ad statements such as "you . . . can lead a normal nearly symptom-free life again" as conveying a false message of universal efficacy that artificially inflated price and demand. The appellate court affirmed the dismissal of the complaint, holding that the claims in the alleged ads were well within what federal law permits and not actionable as a matter of law. *Id.* at 177.

Plaintiffs also renew their challenge to AstraZeneca's decision to market Nexium at all. They contend that the FDA "did not affirmatively authorize marketing of a drug that merely extends the market power of an older drug." Opp. at 9. Hyperbole about "market power" aside, that is what the FDA did. The FDA authorized AstraZeneca to market Nexium in a 40 mg dose for healing erosive esophagitis, fully aware of the relative efficacy of Prilosec and the views of its medical reviewer, and with summaries of clinical studies showing higher rates of healing and faster symptom relief for erosive esophagitis with Nexium 40 mg over Prilosec 20 mg. This decision was within the FDA's exclusive jurisdiction, and Plaintiffs may not launch a collateral

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[3] Clinical studies that compared varying dosages of Nexium to placebo provided evidence of safety and efficacy for maintenance of healing of erosive esophagitis and treatment of symptomatic GERD. *See* RJN Ex. 1, at 16-20.

attack upon it.[4] *See* 21 U.S.C. § 355(a); *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-53 (2001).

b. Plaintiffs' Theory That AstraZeneca Falsely Implies That Healing And Relief Are Not Possible With Prilosec Is Not Actionable

Recognizing these defects in their original claim, Plaintiffs now introduce a new claim. They allege that the ads convey a different implied message that is outside the labeling: that by saying healing is "possible" with Nexium, AstraZeneca is falsely implying that healing and relief were "not" possible with Prilosec. Opp. at 7-8. That claim is not actionable for three independent reasons.

First, there is no allegation that any consumer, let alone any third-party payor or doctor, ever was misled in this manner, and the Complaint forecloses any such assumption. It is inconceivable that, for years, third-party payors were paying for, and doctors were prescribing, Prilosec, making it what Plaintiffs allege to be the most widely prescribed drug in the world (Compl. ¶ 2), without realizing that it was "possible" that Prilosec would provide the relief and healing for which it is indicated. *See* Prilosec Labeling at 15-16 (RJN, Ex. 2). The new claim conflicts with the whole theory of the Complaint: that AstraZeneca falsely implied that Nexium was better at doing what Prilosec already does.

Second, Plaintiffs' claim is far too sweeping to be actionable under Delaware law. The very same argument could be made with respect to any competing product – that by claiming the

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[4] Not only is any collateral attack preempted, it also is barred by the *Noerr-Pennington* doctrine. Plaintiffs argue that the *Noerr-Pennington* doctrine is inapplicable to AstraZeneca's advertising of Nexium. *See* Opp. at 27. To the extent Plaintiffs challenge the decision to seek approval of the 40 mg dose of Nexium, the clinical studies that support approval of the 40 mg dose, and the legitimacy of marketing that is supported by the 40 mg dose, their claims necessarily depend on a challenge to AstraZeneca's conduct in obtaining approval for Nexium. *See, e.g.,* Compl. ¶¶ 80, 155(e). Such conduct is squarely protected. *See* Defs. Br. at 26-27.

manufacturer's new product is effective, the manufacturer necessarily implies that its competitors' or its older products are *in*effective. It simply is not the law that for a manufacturer to say one true thing about its product, it must also say whether the same thing is true about its other products, or about competing products. *Cf. New Jersey Citizen Action*, 842 A.2d at 177. Delaware law, the FDCA, and the DCFA safe harbor all permit a manufacturer to speak about its product in truthful ways. *E.g.,* 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e); 6 *Del. C.* § 2513(b)(2).

Third, this is precisely the sort of speculative theory about potentially false implicit messages that is not actionable under the First Amendment. Plaintiffs do not dispute that: (1) while States may impose restrictions on commercial speech that is false or "inherently misleading," States may not impose restrictions on speech that only is "potentially misleading" by implication unless they can meet the demands either of strict scrutiny or at the very least, of intermediate scrutiny; (2) whether particular speech is false or "inherently misleading" is "a question of law;" or (3) although States have latitude to restrict false or "inherently misleading" commercial speech, States may not define what is false or "inherently misleading" so broadly as to give any State unfettered discretion to edit commercial speech. Defs. Br. at 27 (citing authorities). Plaintiffs assert only that AstraZeneca's ads are not constitutionally protected because they are "false, deceptive and misleading." Opp. at 23. This argument assumes its conclusion, and is non-responsive. AstraZeneca's point is not that States are precluded from restricting commercial speech that is false or "inherently misleading," but that, as a matter of law, Plaintiffs' strained efforts to find an implicitly misleading message in AstraZeneca's advertisements are insufficient, as a matter of law, to allege a statement that is false or "inherently misleading." Plaintiffs offer no response to this core point.

Ads that are alleged to imply a false message merely by omitting certain facts – such as the comparative efficacy of competing products – are not "inherently misleading," as a matter of law. *See, e.g., Western States Med. Ctr. v. Shalala*, 69 F. Supp. 2d 1288, 1299-300 (D. Nev. 1999), *aff'd in part, rev'd in part*, 238 F.3d 1090 (9th Cir. 2001), *aff'd sub nom. Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002); *Texans Against Censorship, Inc. v. State Bar of Texas*, 888 F. Supp. 1328, 1361 (E.D. Tex. 1995). Plaintiffs attempt to distinguish *Western States* and *Texas Against Citizenship* as cases in which the speech in question was "not actually false," "a less restrictive alternative to a complete ban was available," and there was no evidence that the speech in question misled consumers. Opp. at 24. These distinctions are unavailing because the same factors are present here. First, Plaintiffs' Complaint does not allege that any statement in any AstraZeneca ad is "actually false." *See supra*. Rather, Plaintiffs allege only that certain statements in AstraZeneca's ads are "deceptive," "misleading," or create a "false impression" because they imply certain things or omit certain information. *E.g.*, Compl. ¶¶ 114, 125, 127, 131, 133, 135, 137, 145. This is exactly the type of challenge rejected in *Western States* and *Texans Against Citizenship*. Second, the only "alternative" Plaintiffs suggest is a disclosure concerning a non-approved dosing regimen that the FDA bars AstraZeneca from making. *See supra*. Third, as explained in Defendants' Opening Brief, at 34-35, Plaintiffs do not even allege that they saw any of AstraZeneca's ads, let alone that they were misled by them.[5]

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[5] Plaintiffs' reliance on *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996), *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993), *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980), *Friedman v. Rogers*, 440 U.S. 1 (1979), *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781 (3d Cir. 1999), and *In re Warfarin Sodium Antitrust Litig.*, 1998 WL 883469 (D. Del. 1998), *rev'd*, 214 F.3d 395 (3d Cir. 2000), is misplaced. None of those cases dealt with a situation where the challenged ads either (a) were alleged only to imply a misleading message by omitting certain facts, or (b) were not alleged to be inconsistent with a product's federally-approved labeling.

Under Plaintiffs' theory, an ad is stripped of First Amendment protection, even if every statement in the ad is undisputedly true, if some plaintiff believes that those true statements create an implicit message that is misleading. Plaintiffs' interpretation of the law would lead to a proliferation of false advertising and Lanham Act lawsuits that would eviscerate the constitutional protection afforded to commercial speech.

For this reason, it is critical that courts not permit litigation challenging commercial speech to proceed absent a viable allegation of falsity. *Cytyc* illustrates this point. In *Cytyc*, the plaintiff identified thirty statements in defendants' ads and other materials that the plaintiff alleged were false and misleading. *Cytyc*, 12 F. Supp. 2d at 299. In ruling on the defendants' motion to dismiss, the court determined that fourteen of the thirty statements were "non-actionable, and therefore w[ould] not be the subject of discovery or proof at trial," because they were consistent with the product's FDA-approved labeling (and many of the remaining statements were non-actionable puffery). *Id.* at 301. Here, Plaintiffs have failed even to allege that any statement in any AstraZeneca ad is inconsistent with the FDA-approved Nexium labeling. Thus, like the statements in *Cytyc*, Plaintiffs' claims are not actionable.

Plaintiffs' response to AstraZeneca's showing that their claims constitute impermissible government-compelled speech is equally unavailing. Plaintiffs' argument that their failure to specify the injunctive relief they seek renders a compelled speech analysis "premature" (Opp. at 28) conflicts with their Complaint and does not answer AstraZeneca's point that the First Amendment bars the disclosures whose absence, according to the Complaint, rendered the Nexium ads deceptive. Plaintiffs also are incorrect when they argue that even if AstraZeneca's compelled speech argument barred their claims for injunctive relief, it "would not warrant dismissal of plaintiffs' damage claims." Opp. at 28. As one of the cases Plaintiffs cite makes

clear, the "[i]mposition of civil liability, such as the award of money damages, is treated no less stringently than direct regulation of speech." *Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 792 (3d Cir. 1999).

3. Plaintiffs' Remaining Arguments Are Unavailing

Plaintiffs' remaining attempts to avoid the DCFA safe harbor and preemption fare no better. Plaintiffs claim that the FDA does not address consumer deception, and, therefore, the safe harbor and federal preemption do not apply to their claims. Opp. at 11; *see also id.* 9-12, 17-19. This misguided argument does not answer whether Plaintiffs' claims conflict with or stand as an obstacle to federal law, and is irrelevant to the construction of Delaware law. *See Lawrence County*, 469 U.S. at 260 ("a state statute may nevertheless be invalid under the Supremacy Clause if it conflicts with federal law or 'stands as an obstacle to the accomplishment of the full purposes and objectives of Congress'") (citation omitted); *Dowhal*, 88 P.3d at 7, 11 (same). The contention is also demonstrably false.

The FDA has express statutory authority over prescription drug advertising. 21 U.S.C. § 352(n); *see also id.* §§ 321(n), 331(a), 352(a). The FDA has numerous options for addressing advertising that does not comply with the agency's detailed regulatory requirements. *See* 21 U.S.C. § 332 *et seq.* (seizure, injunction, criminal fines, imprisonment); *cf. United States v. Park*, 421 U.S. 658 (1975) (strict criminal liability of CEO for violations of the FDCA). Contrary to Plaintiffs' suggestion, the FDA actively polices comparative drug claims.[6]

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[6] *See, e.g.,* Letter from Thomas W. Abrams, Director, FDA Division of Drug Marketing, Advertising, and Communications ("DDMAC"), to Cary Rayment, President and Chief Executive Officer, Alcon Laboratories, Inc., at 2 (Apr. 27, 2005), *available at* http://www.fda.gov/cder/warn/2005/Cipro-13122.pdf (last visited August 24, 2005) (addressing "Unsubstantiated Superiority Claims – Efficacy"); *id.* ("These claims suggest that CIPRO® HC OTIC is superior to other products in the treatment of otitis externa in that it ends the pain 19 hours sooner."); Letter from Thomas W. Abrams, Director, DDMAC, to Michael W. Bonney, (continued . . .)

Moreover, the Federal Trade Commission agrees that the FDA should exercise primary responsibility for regulating advertising of prescription drugs. *Working Agreement Between FTC and Food and Drug Administration*, 4 Trade Reg. Rep. (CCH) ¶ 9851 (1971); *see also United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 763 (6th Cir. 1999) ("One of the primary goals of the FDCA is to protect consumers from economic harm.").[7] Plaintiffs' reliance on *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990), thus is misplaced. In that case, the court was addressing the advertising of an over-the-counter drug, over which the FDA and the FTC have agreed the FTC exercises primary authority. *Id.* at 227; *Working Agreement*, 4 Trade Reg. Rep. (CCH) ¶ 9851 (1971). With respect to advertising of prescription drugs, however, the FDA's authority is primary. *Id.*

Plaintiffs' remaining authorities on preemption also are inapposite. Plaintiffs place great reliance on a hypothetical from *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 349-50 (2d Cir. 2003). But the word "preemption" is nowhere to be found in that case. The proffered passage is offered only to illustrate a principle of causation. Because the decision and hypothetical had nothing to do with preemption, the court had no occasion to address the issues of preemption

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(. . . continued)
President and Chief Executive Officer, Cubist Pharmaceuticals, at 4 (Aug. 17, 2004), *available at* http://www.fda.gov/cder/warn/2004/Macmis12433final.pdf (last visited August 24, 2005) (addressing "Misleading Comparative Claim" that Cubicin "is superior to other antibiotics intended for the same conditions").

[7] The FDA has express statutory authority to address economic concerns, including gross deception of consumers, and economic fraud is one of the agency's express priorities. *E.g.*, 21 U.S.C. § 375(b) (statutory publicity authority to address situations involving "imminent danger to health or gross deception of the consumer"); FDA Compliance Policy Guide, § 120.500 (CPG 7150.10), *available at* http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg120-500.html (last visited August 24, 2005); *see also* 21 U.S.C. § 352(a) (drug is misbranded if labeling is "false or misleading *in any particular*") (emphasis added); *id.* § 352(e)(1)(A) (labeling must disclose "established names" of drug, so doctors may identify and prescribe generic alternatives).

(*e.g.*, that *Buckman* would squarely preempt the state law claim envisaged in the hypothetical) that makes Plaintiffs' use of this hypothetical for preemption purposes grossly misleading.[8]

II. PLAINTIFFS IDENTIFY NO ALLEGATIONS THAT AFFORD THEM STANDING

Plaintiffs concede that in order to have standing to bring this action, they must allege "a causal connection between the injury and the conduct complained of." Opp. at 29. Plaintiffs' Complaint, however, fails to plead facts that would support any finding of causation. Rather than address this failure, Plaintiffs' Opposition relies on inapposite cases in an attempt to circumvent the causation requirement.

A. The Individual Plaintiffs Have Failed To Allege Standing

Individual Plaintiffs do not dispute that they fail to allege: (1) that any allegedly misleading ad for Nexium caused their doctors to prescribe Nexium to them; (2) what medication their doctor would have prescribed for them in place of Nexium; and (3) what they would have paid, out-of-pocket, for that medication as compared to what they did pay for Nexium. These failures are fatal to their efforts to establish causation of economic injury.

Plaintiffs' reliance upon *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395 (3d Cir. 2000), is unavailing. Plaintiffs ignore that in *Warfarin*, DuPont was alleged to have "dominated the oral anti-coagulant market for over 30 years" with its branded drug Coumadin (warfarin sodium), and to have "orchestrated a campaign disparaging" generic warfarin sodium substitutes, raising the generic manufacturer's cost to enter the market and disabling its market penetration. *Id.* at 397. The consumer plaintiffs claimed that by thwarting market entry by cheaper generic

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[8] In *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1331 (3d Cir. 1995), there was no indication that the statements that formed the basis of the plaintiff's fraud claim were within the FDA-approved labeling, and the court in any event was construing an express preemption clause that does not apply here. In *Morelli v. Weider Nutrition Group, Inc.*, 712 N.Y.S.2d 551 (1st Dep't 2000), the

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drugs, DuPont effectively forced them to purchase Coumadin. *Id.* The Third Circuit held that, because Coumadin was the only drug available, the plaintiffs had "no choice in which warfarin sodium they purchased." *Id.* at 401. That holding illustrates the causation defects in the claims alleged here.

First, Plaintiffs have not alleged that they had no choice but to purchase Nexium. They could not do so because there are several other PPIs, as well as Prilosec, on the market. *See* Compl. ¶¶ 4, 51. The factual premise that creates causation in the Coumadin case – that consumers had "no choice" but to buy Coumadin – is thus entirely missing here.

Second, the plaintiffs in *Warfarin* alleged that the consumers themselves had paid inflated prices for Coumadin as a result of DuPont's actions. 214 F.3d at 398; *see also Desiano*, 326 F.3d at 345. The individual Plaintiffs here allege only that they "purchased" or "ma[de] co-payments" for Nexium, not that they paid more for Nexium than they would have paid for any other PPI they would have purchased. Compl. ¶¶ 19-22. Plaintiffs thus do not satisfy the rudimentary requirement of alleging economic injury, let alone causation.

Instead, Plaintiffs seek to rely on the "fraud-on-the-market" theory to circumvent the causation requirement under Delaware law. A New Jersey appellate court, however, already has rejected Plaintiffs' counsel's attempt to apply this theory to New Jersey's DCFA analog. *New Jersey Citizen Action*, 842 A.2d at 178. Such an attempt should be no more successful here than it was in New Jersey and other states. Although Plaintiffs assert at one point that they are not actually asserting a fraud-on-the-market theory, because "the Nexium price points were the product of affirmative decision-making by AstraZeneca," (Opp. at 32 at n.17), Plaintiffs

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court also was construing an express preemption clause.

expressly allege that their injuries were caused by market forces, namely that AstraZeneca's advertisements "artificially create[d] demand for Nexium at an artificially inflated price." Compl. ¶ 159; *see also* ¶ 135, 137, 139, 141, 143, 145. Indeed, Plaintiffs do no contest that they have failed to allege that any of the Plaintiffs were misled by, or even were exposed to, AstraZeneca's advertisements. While Plaintiffs need not plead reliance under the DCFA, they must still allege that AstraZeneca caused them injury.[9] *Interfaith Cmty. Org. v. Honeywell Int'l, Inc.*, 399 F.3d 248, 254-55 (3d Cir. 2005); *Stephenson v. Capano Devel.*, 462 A.2d 1069, 1077-78 (Del. 1983). Their fraud-on-the-market theory is merely a thinly veiled and impermissible attempt to circumvent that causation requirement.

Plaintiffs further contend that the "learned intermediary doctrine" does not bar their claim because they have alleged that doctors, in general, were misled by AstraZeneca. Opp. at 35. However, Plaintiffs' general allegations cannot replace specific allegations concerning the cause of Individual Plaintiffs' own alleged injuries. *Weiner v. Bank of King of Prussia*, 358 F. Supp. 684, 694 (E.D. Pa. 1973) ("A plaintiff may not use the procedural device of a class action to boot strap himself into standing he lacks under the express terms of the substantive law."). They also suggest that the New Jersey Supreme Court's rejection of the learned intermediary doctrine in certain duty-to-warn cases is somehow applicable to this case. The doctrine, however, is merely a manifestation of a basic principle of causation that applies where a product is obtained in reliance on an intermediary, which is not abrogated by a court's conclusion that a prescription drug manufacturer may not satisfy its duty to warn through warnings to the physicians in cases

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[9] Plaintiffs must plead justifiable reliance for their negligent misrepresentation claim. *See H-M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 142 (Del. Ch. 2003). Plaintiffs do not contend that they have alleged reliance, and their negligent misrepresentation claim, therefore, must be dismissed.

involving direct-to-consumer advertising.[10] *See, e.g., Shannon v. Boise Cascade Corp.*, 805 N.E.2d 213, 219 (Ill. 2004) (holding that in a false advertising action brought by home owner where builder of home decided what materials would be used in construction, a failure to prove that builder was deceived by misrepresentations defeated causation).

B. The Third-Party Payor Plaintiffs Have Failed To Allege Standing

The Third-Party Payor Plaintiffs have also failed to plead standing because none has pleaded causation, for the same reasons described above for the Individual Plaintiffs. Ironically, *Desiano,* 326 F.3d 339, which Plaintiffs wrongly rely upon for preemption (*see* pgs. 15-16, *supra*), properly serves only to expose the failure of the third-party payor plaintiffs here to plead causation. The third-party payor plaintiffs in *Desiano* alleged that, had they not been deceived by the defendants' misrepresentations about the safety of *Rezulin*, they would have taken steps – such as "to exclude it altogether from their approved schedules, set a low scheduled value, set a high copay obligation, and otherwise dissuade doctors from prescribing it" – so as not to purchase Rezulin at the prices set by the defendants. *Id.* at 349 n.9. The Complaint here lacks any comparable allegations. Absent such allegations, Plaintiffs have failed to allege causation, and their claims must be dismissed.

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[10] In *Perez v. Wyeth Labs.*, 734 A.2d 1245 (N.J. 1999), the New Jersey considered whether a manufacturer's duty to warn was satisfied by warnings to physicians where the manufacturer advertised the product directly to consumers. The court concluded that in such circumstances, the duty to warn ran to the ultimate consumers as well. *Id.* at 1257-58. The court had no occasion to consider the causation questions presented here. In any event, the court's abrogation of the learned intermediary doctrine in DTC cases has not been adopted in other jurisdictions. *See In re Meridia Prods. Liab. Litig.,* 328 F. Supp. 2d 791, 812 n. 19 (N.D. Ohio 2004) (noting that no other jurisdiction has adopted *Perez*); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 766 (Ky. 2004) (same). Delaware continues to recognize the doctrine.

C. The Associational Plaintiffs Have Failed To Allege Standing

Plaintiffs do not contest that the Associational Plaintiffs lack standing to bring these actions in their own right, and instead rely on "associational standing." This claim must fail because they have not alleged that any of their members suffered an injury caused by AstraZeneca's alleged actions. Plaintiffs instead simply allege that their members, like the Individual Plaintiffs, "used and paid for Nexium and have been injured by the unlawful conduct alleged herein." Compl. ¶¶ 23-25. This is insufficient to for these reasons set forth above. Even if Plaintiffs had properly pleaded associational standing, Plaintiffs do not contest that the Associational Plaintiffs lack standing to bring claims for damages. Opp. at 37. Those claims must, therefore, be dismissed.

CONCLUSION

For all of the foregoing reasons, Plaintiffs have failed to state any claim upon which relief can be granted, this Court lacks subject matter jurisdiction, and their Complaint should be dismissed with prejudice.

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CERTIFICATE OF SERVICE

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